Rapid Data Analysis – Systemic fluoroquinolones and thrombotic thrombocytopenic purpura (TTP)

First published: 25/08/2021

Last updated: 25/08/2021

Study Finalised

Administrative details

EU PAS number

EUPAS42641

Study ID

42642

DARWIN EU® study

No

Study countries

- ☐ Germany
- ☐ United Kingdom

Study description

Fluoroquinolone antibiotics (of which ciprofloxacin is an example) are widely used for the treatment of certain types of microbial infection. Recently, their use has been reported as being associated with the onset of Thrombotic Thrombocytopenic Purpura (TTP), a rare but potentially fatal disease that causes blood clots to form in small blood vessels throughout the body. This issue is being evaluated by the European Union's Pharmacovigilance Risk Assessment Committee (PRAC), a regulatory body responsible for assessing and monitoring the safety of human medicines. This study simply describes how often TTP occurs after patients are prescribed fluoroquinolones. To allow contextualisation of the results, the same analysis has been done in two other groups of patients prescribed other antibiotic medicines. The first group are patients prescribed broad spectrum penicillins. The second group are patients who have been prescribed azithromycin. The results of this study will be used by the PRAC in its decision-making process by helping to decide if regulatory action needs to be taken to protect patients taking fluoroquinolones.

Study status

Finalised

Research institutions and networks

Institutions

European Medicines Agency (EMA)

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Institution

Contact details

Study institution contact

EMA EMA ICU@ema.europa.eu

Study contact

ICU@ema.europa.eu

Primary lead investigator

EMA EMA

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/06/2021

Actual: 01/06/2021

Study start date

Planned: 01/06/2021

Actual: 01/06/2021

Date of final study report

Planned: 25/08/2021

Actual: 25/08/2021

Sources of funding

- EMA

Study protocol

Analysis-Plan_fluoroquinolones_TTP.pdf (497.61 KB)

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

Is there evidence of an association between systemic fluoroquinolones and acquired TTP? (i.e. is there an increased frequency of acquired TTP following treatment with fluoroquinolones?)

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(J01MB) Other quinolones

Other quinolones

Medical condition to be studied

Thrombotic thrombocytopenic purpura

Population studied

Short description of the study population

Patients with a first prescription for either a systemic fluoroquinolone or a systemic broad-spectrum penicillin (or azithromycin). Only the first prescription

date for either of the two types of antibiotics was considered. Patients with a concomitant first prescription for both a systemic fluoroquinolone and a systemic broad-spectrum penicillin (or azithromycin), and patients with a history of TTP were excluded.

Age groups

- Preterm newborn infants (0 – 27 days)
- Term newborn infants (0 – 27 days)
- Infants and toddlers (28 days – 23 months)
- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)
- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Estimated number of subjects

10000

Study design details

Data analysis plan

The incidence rate of TTP was calculated from the number of patients with TTP during the follow-up period and the total follow-up time in years of follow-up in each of the two treatment groups. The 95% confidence intervals for the incidence rates were calculated.

Documents

Study results

Final_report_fluoroquinolones_TTP 20210824.pdf (848.55 KB)

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data source(s)

THIN® (The Health Improvement Network®)

Data source(s), other

THIN, IQVIA Disease Analyzer Germany

Data sources (types)

Electronic healthcare records (EHR)

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No